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No. 15-446

In the Supreme Court of the United States

CUOZZO SPEED TECHNOLOGIES, LLC,
Petitioner,

v.

MICHELLE K. LEE, Under Secretary of Commerce
for Intellectual Property and Director,
Patent and Trademark Office,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

AMICUS CURIAE BRIEF OF MYLAN PHARMACEUTICALS INC. SUPPORTING RESPONDENT

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Amicus curiae Mylan Pharmaceuticals Inc. submits this brief supporting Respondent.[1]

STATEMENT OF INTEREST

Mylan is one of the largest generic and specialty pharmaceutical manufacturers in the world. It is dedicated to providing greater public access to high-quality medicines by bringing lower-priced drugs to the market when and where they are needed. To that end, Mylan often challenges suspect patents before district courts and the Patent and Trademark Office (PTO) because invalid patents hamper the flow of commerce and keep more affordable medicines from the public.

Since Congress passed the America Invents Act (AIA), Mylan has instituted numerous *inter partes* reviews (IPR) that have employed the broadest-reasonable-interpretation standard. Mylan files this amicus brief because it believes that the PTO's decision to adopt that long-used standard advances Congress's goal of creating an expedited and cost-effective process for ferreting out bad patents. Second-guessing that decision would throw ongoing IPR proceedings into disarray (including many to which Mylan is a party), but more importantly, it could discourage would-be

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[1] In accordance with Supreme Court Rule 37.6, *amicus curiae* states that no counsel for a party authored this brief in whole or in part and that no party or counsel for a party helped fund the preparation or submission of the brief. No person other than *amicus curiae* or their counsel funded work on the brief.

On February 3, 2016, Cuozzo filed a letter consenting to the filing of *amicus* briefs. On March 16, 2016, Mylan notified the Solicitor General of its intent to file an *amicus* brief; the next day, the Solicitor General sent a letter consenting to the filing of the brief.

patent challengers from challenging overbroad, invalid patents that never should have issued in the first place. The end result is that the public may miss out on important and competitively priced medicines.

INTRODUCTION AND SUMMARY OF ARGUMENT

The cascade of policy arguments in Petitioner Cuozzo's brief (and in the briefs of its supporting *amici*) suggests that this case comes to the Court on a clean slate—that the Court must decide in the first instance which claim-construction standard should apply in IPR. That, of course, is not correct. Congress has spoken through the AIA, and the PTO has spoken through federal regulations, so this Court faces a more modest task: It must decide (1) whether the AIA vests the PTO with authority to set the claim-construction standard for IPR and (2) if so, whether the agency's choice of the broadest-reasonable-interpretation standard is a "permissible construction of the statute." *Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 866 (1984).

Those questions fade to the background in Cuozzo's brief, and for good reason: The AIA is silent about which claim-construction standard should apply in IPR, but Congress vested the PTO with broad authority to fill the gap and "prescribe regulations establishing and governing inter partes review." 35 U.S.C. § 316(a)(4). In using the unqualified word "governing," Congress did not grant the PTO a small crumb of interpretative authority; it granted the agency wide authority over *every* aspect of IPR on which Congress has not otherwise spoken (and spoken plainly). *See Nat'l Cable & Telecomm. Ass'n v. Brand X*

Internet Servs., 545 U.S. 967, 982 (2005) ("*Chevron* established a presumption that Congress, when it left ambiguity in a statute meant for implementation by an agency, understood that the ambiguity would be resolved, first and foremost, by the agency, and desired the agency (rather than the courts) to possess whatever degree of discretion the ambiguity allows.") (internal quotation marks omitted).

Unwilling to give the word "governing" its natural meaning, Cuozzo and its supporters instead strain to import a meaning not found in the statute. They argue that Congress gave the PTO broad authority to promulgate "procedural" rules but not "substantive" ones. The statute does not draw that distinction; it exists only in the pages of Cuozzo's and its supporters' briefs. Absent a clear congressional directive to draw such a distinction, this Court should "not waste [its] time in the mental acrobatics needed to decide whether an agency's interpretation of a statutory provision" is substantive or procedural. *City of Arlington v. F.C.C.*, 133 S. Ct. 1863, 1871 (2013) (rejecting as a "mirage" the distinction between "jurisdictional" and "non-jurisdictional" agency interpretations). Unlike in other parts of § 316—where Congress drew fine distinctions between "procedures" and "standards"—Congress did not distinguish between "substance" and "procedure" in § 316(a)(4). These labels are nothing more than an "empty distraction because every new application of a broad statutory term can be reframed" as "substantive" or "procedural," depending on which label suits which party's interests. *Id.* at 1870.

The only remaining question, then, is whether the PTO's decision to employ the broadest-reasonable-

interpretation standard in IPR is a "permissible construction of the statute." *Chevron,* 467 U.S. at 866. This Court's *Chevron* jurisprudence makes clear that "permissible" does not mean "best." It means permissible. "[T]he question in every case is, simply, whether the statutory text forecloses the agency's assertion of authority, or not." *City of Arlington*, 133 S. Ct. at 1871. Here, the answer to that question is no.

To begin with, the broadest-reasonable-interpretation standard did not appear out of thin air; the PTO has employed that standard in a variety of contexts for over 100 years. Courts presume that Congress knew that history when it gave the PTO authority to fashion rules "governing" IPR. *See City of Arlington*, 133 S. Ct. at 1868 ("*Chevron* provides a stable background rule against which Congress can legislate: Statutory ambiguities will be resolved, within the bounds of reasonable interpretation, not by the courts but by the administering agency."); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1277 (Fed. Cir. 2015) ("There is no indication that the AIA was designed to change the claim construction standard that the PTO has applied for more than 100 years."). Indeed, the AIA's legislative history suggests that Congress not only understood that the PTO might adopt the broadest-reasonable-interpretation standard for IPR but also may have *wanted* the agency to do so. *See* 157 Cong. Rec. 3428 (2011) (statement by Senator Kyl acknowledging that the "broadest reasonable construction" standard would apply in IPR).

The reason why is plain. Employing the broadest-reasonable-interpretation standard in IPR is consistent with Congress's directive that the PTO consider "the

effect of any regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete [IPR] proceedings." 35 U.S.C. § 316(b). Applied correctly, the standard will reduce questionable patent litigation by ridding the system of invalid patents that never should have issued while also providing those who hold good patents a more efficient forum for defending against invalidity claims. *See* 35 U.S.C. § 315(e)(2) (prohibiting IPR petitioners from later challenging a patent's validity in district court or the ITC). In any event, whatever one thinks about those or other policy justifications, the dispositive point is the lack of "statutory text [that] forecloses" the PTO's decision to adopt the broadest-reasonable-interpretation standard for IPR. *City of Arlington*, 133 S. Ct. at 1871.

For their part, Cuozzo and its supporters see the broadest-reasonable-interpretation standard as a repudiation of Congress's intent to make IPR "adjudicatory" in nature. From Congress's *expressed* intent to make IPR an adjudicatory proceeding, Cuozzo and its supporters divine an *unspoken* intent to make IPR mirror district-court litigation, right down to the claim-construction standard.

That argument suffers from many flaws, not the least of which is that it has no basis in the statutory text. If anything, the statute shows that Congress did not intend IPR to be district-court litigation by another name. For instance, unlike in patent litigation, a respondent in IPR can amend its patent claims at least once to propose narrower substitute claims. 35 U.S.C. § 316(d). On top of that, different pleading and

evidentiary standards apply in IPR. *See* 35 U.S.C. §§ 314(a), 316(e). Further still, discovery is much narrower in IPR. *See id.* § 316(a)(5). IPR cannot stretch on for years and years; it usually must conclude within a year after institution. *See id.* § 316(a)(11). The list of differences goes on, refuting the notion that Congress intended IPR to be a copycat surrogate for patent litigation.

Finally, Cuozzo's argument that the broadest-reasonable-interpretation standard will wreak havoc in the patent world is one best directed to Congress, not to this Court. "The proper *Chevron* inquiry is not whether the agency construction can give rise to undesirable results " *Barnhart v. Thomas*, 540 U.S. 20, 29 (2003). An agency can make a reasonable choice that ends up producing some negative consequences (*Chevron*, 467 U.S. at 843); it is up to Congress to address those consequences.

At any rate, the notion that the broadest-reasonable-interpretation standard will destroy the patent system and discourage innovation is overstated at the very least. First, in certain instances, the broadest-reasonable-interpretation standard will produce the same result as the standard that district courts apply Second, the Federal Circuit serves as a backstop against unreasonable applications of the broadest-reasonable-interpretation standard in IPR. And third, Congress or the PTO can always step in if the standard produces more mischief than good—an unlikely scenario given the standard's long history in patent proceedings.

Until then, this Court must defer to the PTO's permissible choice to adopt the broadest-reasonable-interpretation standard for IPR.

On the second question presented, the plain language of 35 U.S.C. § 314(d) mandates that a PTO decision whether to institute an *inter partes* review is "final and nonappealable." Congress could not have spoken more clearly Limiting appeals of IPR to the substance of the "final written decision" (35 U.S.C. § 319) properly focuses the Federal Circuit on the underlying patentability question and avoids unintended consequences and potential conflicts across the patent statutes.

ARGUMENT

"When a court reviews an agency's construction of the statute which it administers, it is confronted with two questions." *Chevron*, 467 U.S. at 842. "First, applying the ordinary tools of statutory construction, the court must determine 'whether Congress has directly spoken to the precise question at issue.'" *City of Arlington*, 133 S. Ct. at 1868 (quoting *Chevron*, 467 U.S. at 842–43). If Congress has, "the [C]ourt, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *City of Arlington*, 133 S. Ct. at 1868 (internal quotation marks omitted). "But if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* "If the agency's answer is based on a permissible construction of the statute, that is the end of the matter." *Id.*

The AIA is silent about which claim-construction standard should apply in IPR, but Congress delegated to the PTO broad authority to "prescribe regulations governing inter partes review." 35 U.S.C. § 316(a)(4). That grant of unqualified authority to the PTO to fashion rules "governing" IPR included the power to select a familiar and often-applied standard to test patentability in IPR. At the very least, the statute plainly does not "foreclose[] the agency's assertion of authority." *City of Arlington*, 133 S. Ct. at 1871.

I. CONGRESS VESTED THE PTO WITH BROAD AUTHORITY TO PROMULGATE RULES "GOVERNING" IPR, AND THAT AUTHORITY INCLUDES THE POWER TO SET THE CLAIM-CONSTRUCTION STANDARD.

An agency action is entitled to *Chevron* deference if "Congress delegated authority to the agency generally to make rules carrying the force of law, and the agency interpretation claiming deference was promulgated in the exercise of that authority." *United States v. Mead Corp.*, 533 U.S. 218, 226–27 (2001). Congress delegates the necessary authority by giving an agency "power to engage in adjudication or notice-and-comment rulemaking " *Id.* at 227; *see also id.* at 230 ("It is fair to assume generally that Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force.").

The AIA instructs the PTO to "prescribe regulations establishing and governing inter partes

review." 35 U.S.C. § 316(a)(4). Exercising that statutory authority, the PTO promulgated regulations governing IPR, including one providing that "[a] claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100. Because that regulation unquestionably is one "governing" IPR, it is entitled to *Chevron* deference. This Court should not disturb the PTO's regulation because it is a permissible construction of the statute.

Yet rather than take the word "governing" at face value or address *Chevron* head-on, Cuozzo and its *amici* manufacture a dichotomy between "substantive" and "procedural" rules. According to them, Congress gave the PTO authority to promulgate procedural rules but not substantive ones. *See, e.g.*, Pet. Br. at 35–42.

There is no trace of that distinction in the AIA. The statute vests the PTO with authority to promulgate rules "governing" IPR. It does not limit that authority to rules "governing procedures in IPR." Cuozzo's substance/procedure dichotomy finds no support in the statute's plain language.[2] *See Hardt v. Reliance*

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[2] That lower federal courts have construed the Patent Act's original delegation to the PTO to "establish regulations" that "shall govern the conduct of proceedings in the Office" (35 U.S.C. § 2(b)(2)(A)) as authorizing only "procedural" rulemaking is of no moment. The AIA is a new law with a new purpose and new, broader language. And in all events, neither this Court nor the PTO is bound by those earlier judicial interpretations. *Nat'l Cable & Telecommunications Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 982 (2005) ("A court's prior judicial construction of a statute trumps an agency construction otherwise entitled to *Chevron* deference only if the prior court decision holds that its construction

Standard Life Ins. Co., 560 U.S. 242, 251 (2010) ("We must enforce plain and unambiguous statutory language according to its terms.").

It is not as if Congress is incapable of drawing those distinctions. "Congress knows to speak in plain terms when it wishes to circumscribe, and in capacious terms when it wishes to enlarge, agency discretion." *City of Arlington*, 133 S. Ct. at 1868. In other parts of § 316, Congress drew distinctions of the sort that Cuozzo wishes Congress would have drawn in § 316(a)(4). For instance, in § 316(a)(3), Congress delegated to the PTO authority to promulgate rules "establishing procedures for the submission of supplemental information after the petition is filed." And in § 316(a)(5), Congress directed the PTO to promulgate rules "setting forth standards and procedures for discovery of relevant evidence," demonstrating that Congress knows how to distinguish procedural regulations from other types of regulations when it wants to. *See also* 35 U.S.C. § 316(a)(9) ("The Director shall prescribe regulations. setting forth standards and procedures ").

Read against those more limited delegations of authority, Congress's use of the unqualified term "governing" in § 316(a)(4) must be read to include more than just "procedural" issues (however defined). Courts presume that Congress uses language intentionally, not superfluously. *See Reiter v. Sonotone Corp.*, 442 U.S. 330, 339 (1979) ("In construing a statute we are

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follows from the unambiguous terms of the statute and thus leaves no room for agency discretion.").

obliged to give effect, if possible, to every word Congress used.").[3]

This is not the first time that a party unhappy with the results of an agency's exercise of statutory authority has tried to draw artificial lines to nullify *Chevron*. Faced with the reality that courts usually defer to an agency's interpretation of a statute committed to its trust (*see* Connor N. Raso & William N. Eskridge, Jr., *Chevron As A Canon, Not A Precedent: An Empirical Study of What Motivates Justices in Agency Deference Cases*, 110 COLUM. L. REV 1727, 1767 (2010)), parties wishing to unwind agency interpretations have taken to "sifting the entrails of vast statutory schemes" in an effort to avoid *Chevron*. *City of Arlington*, 133 S. Ct. at 1871.

But the Court decried such divination in *City of Arlington*, where the City argued that the agency had

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[3] Cuozzo also invokes the *ejusdem generis* canon, arguing that § 316(a)(4) is a "catch-all" delegation over "procedural" matters because the delegations to the PTO in other subsections of § 316(a) are "procedural." Pet. Br. 8–9. The *ejusdem generis* canon "is not relevant here." *CSX Transp., Inc. v. Ala. Dep't of Revenue*, 562 U.S. 277, 294 (2011). Congress's delegation to the PTO to prescribe rules "governing" IPR "'is *not* a general or collective term following a list of specific items to which a particular statutory command is applicable (*e.g.*, 'fishing rods, nets, hooks, bobbers, sinkers, and other equipment').'" *Id.* (internal quotation marks omitted). Instead, it is the fourth of thirteen subsections—just "one of several distinct and independent" provisions. *Id.*

At any rate, Cuozzo paints with too broad a brush in claiming that all the other subsections in § 316(a) are "procedural." Three of them give the PTO authority to set "standards" (differentiated from "procedures"). 35 U.S.C. § 316(a)(2), (5), (9).

overstepped its bounds by promulgating a regulation interpreting its own "jurisdiction." 133 S. Ct. at 1868–69. The City argued—much like Cuozzo's "procedural"/"substantive" distinction here—that Congress gave the F.C.C. authority to regulate "non-jurisdictional" matters but not "jurisdictional" ones. *Id.*

This Court rejected that "false dichotomy between 'jurisdictional' and 'non-jurisdictional' agency interpretations" because it had no basis in the statute and ran counter to the Court's longstanding application of *Chevron* deference to an agency's interpretation of "statutes designed to *curtail* the scope of agency discretion." *City of Arlington*, 133 S. Ct. at 1872. The distinction between "jurisdictional" and "non-jurisdictional" questions was a "mirage" because "[n]o matter how it is framed, the question a court faces when confronted with an agency's interpretation of a statute it administers is always, simply, *whether the agency has stayed within the bounds of its statutory authority.*" *Id.* at 1868.

Cuozzo's proposed dichotomy between "substantive" and "procedural" questions is the same mirage. There is no basis—*none*—in the AIA for Cuozzo's purported distinction.[4] It is no different from the "jurisdictional"/"non-jurisdictional" distinction rejected

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[4] The PTO has adopted the broadest-reasonable-interpretation standard in other contexts without challenge. The PTO has, for instance, adopted the same broadest-reasonable-interpretation standard—through notice and comment rulemaking—for both post-grant review proceedings and covered business-method-patent proceedings. *See* 37 C.F.R. § 42.200(b), 37 C.F.R. § 42.300(b). And yet no one has suggested that those regulations are invalid because they were "substantive" as opposed to "procedural."

in *City of Arlington*. Both are backdoor attempts to avoid *Chevron* by questioning the scope of the agency's delegated authority—which the challenger in *City of Arlington* called "jurisdiction." *Compare City of Arlington*, 133 S. Ct. at 1868 ("The question here is whether an agency's interpretation of a statutory ambiguity concerns the scope of the agency's statutory authority (that is, its jurisdiction)."). Given the close identity between Cuozzo's challenge and the challenge in *City of Arlington*, this Court's prophetic warning in *City of Arlington* sees some fulfilment in Cuozzo's positions here:

> The false dichotomy between "jurisdictional" and "nonjurisdictional" agency interpretations may be no more than a bogeyman, but it is dangerous all the same. Like the Hound of the Baskervilles, it is conjured by those with greater quarry in sight: Make no mistake—the ultimate target here is *Chevron* itself. Savvy challengers of agency action would play the "jurisdictional" card in every case. Some judges would be deceived by the specious, but scary-sounding, "jurisdictional"-"non-jurisdictional" line; others tempted by the prospect of making public policy by prescribing the meaning of ambiguous statutory commands. The effect would be to transfer any number of interpretive decisions—archetypal *Chevron* questions, about how best to construe an ambiguous term in light of competing policy interests—from the agencies that administer the statutes to federal courts.

133 S. Ct. at 1872–73.

The AIA's plain language forecloses that kind of power transfer to the courts. Through the statute, Congress broadly delegated to the PTO authority to "prescribe regulations governing inter partes review." 35 U.S.C. § 316(a)(4). That grant of interpretative authority admits of no ambiguity: Regulations "governing" IPR plainly encompass standards for assessing patent validity. But even if the AIA's delegation of authority to the PTO were ambiguous as to the scope of authority prescribed, this Court "must defer under *Chevron* to an agency's interpretation of a statutory ambiguity that concerns the scope of the agency's statutory authority (that is, its jurisdiction)." *City of Arlington*, 133 S. Ct. at 1868. This Court likewise should and must defer to the PTO's assertion of authority over the claim-construction standard to be used in IPR.

The only remaining question, then, is whether the PTO's choice of the broadest-reasonable-interpretation standard is a "permissible" construction of the statute. *See Brand X*, 545 U.S. at 982. For the many reasons set out below, the answer is yes.

II. THE PTO'S DECISION TO USE THE BROADEST-REASONABLE-INTERPRETATION STANDARD IS ENTITLED TO DEFERENCE.

Cuozzo leaves nothing on the field in an effort to persuade the Court that Congress intended for IPR to be governed by the ordinary-meaning standard that district courts apply. For more than thirty pages in its brief, Cuozzo tries to discover congressional intent about claim construction from a statute that everyone agrees says nothing about claim construction. *See In re*

Cuozzo Speed Techs., 793 F.3d at 1275 (the AIA does "not resolve the issue of whether the broadest reasonable interpretation standard is appropriate in IPRs; it is silent on that issue").

Rather than set the claim-construction standard itself, Congress delegated that authority—to "prescribe regulations governing inter partes review"—to the PTO. 35 U.S.C. § 316(a)(4). The PTO chose the broadest-reasonable-interpretation standard. This Court must defer to that choice unless it was "procedurally defective, arbitrary or capricious in substance, or manifestly contrary to the statute." *Mead Corp.*, 533 U.S. at 227

Far from being arbitrary or capricious, the PTO's choice was not only reasonable but what Congress likely intended. Through the AIA, Congress directed the PTO when developing its regulations to "consider the effect of any such regulation on the economy, the integrity of the patent system, the efficient administration of the Office, and the ability of the Office to timely complete proceedings instituted under this chapter." 35 U.S.C. § 316(b). No claim-construction standard better serves those goals than the broadest-reasonable-interpretation standard. That standard draws on the PTO's experience employing the standard in proceedings where claim amendments are allowed while at the same time promoting Congress's goal of creating a "quick and cost effective alternative[] to litigation." H.R. REP NO. 112-98, pt. 1, at 48 (2011). Applying the *Chevron* deference that the PTO deserves, the PTO's choice of the broadest-reasonable-interpretation standard is permissible and certainly not foreclosed by the statute.

A. For nearly 100 years, the PTO has applied the broadest-reasonable-interpretation standard in contexts where the patentee has a right to amend its claims.

The PTO has applied the broadest-reasonable-interpretation standard in various contexts for nearly a century In 1924, the D.C. Circuit blessed the standard for initial patent examinations. *In re Carr*, 297 F 542 (D.C. Cir. 1924). "This rule is a reasonable one," the court said, because it "tends not only to protect the real invention, but to prevent needless litigation after the patent has issued." *Id.* at 544. Over the years, the courts of appeals have approved the standard in other contexts, including *inter partes* reexamination (the predecessor to IPR). *See Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1352 (Fed. Cir. 2013); *see also In re Yamamoto*, 740 F.2d 1569, 1571–72 (Fed. Cir. 1984) (*ex parte* reexaminations).

Courts have done so for good reason: As the Federal Circuit has recognized (and no one seriously disputes), "[g]iving claims their broadest reasonable construction 'serves the public interest by reducing the possibility that claims, finally allowed, will be given broader scope than is justified.'" *Yamamoto*, 740 F.2d at 1571. Otherwise, overbroad and invalid patents will continue to harm the integrity of the patent system and the economy by blocking competition and roping off the field to further innovation.

Cuozzo plays up that IPR differs in some respects from those other contexts, but again, Cuozzo misses the point: The question is not whether the PTO's choice of standard fits comfortably with past practice. It is

whether it is permissible given the delegation of authority to the agency in the AIA and, correspondingly, the purposes that lie behind that statute. The PTO could have permissibly chosen the broadest-reasonable-interpretation standard even if IPR had no analog in other patent-office proceedings. Through the AIA, Congress directed the PTO to promulgate rules that protect "the integrity of the patent system" (35 U.S.C. § 316(b)) by creating a timely and cost-effective process for ferreting out improvidently granted patents. *See In re Cuozzo Speed Techs.*, 793 F.3d at 1285 (Newman, J., dissenting) (describing goal to "facilitat[e] the removal of patents that were improvidently granted"). A broader claim-construction standard, which captures a wider swath of prior art, is the best—or, at the very least, a reasonable—method for achieving that goal. It ensures, to the greatest extent possible, that a patent is novel and non-obvious by testing it against the totality of relevant art. That, of course, is not only a permissible goal, but exactly what Congress intended.

But the Court does not have to go that far to resolve this case: The broadest-reasonable-interpretation standard has *always* applied across a spectrum of proceedings—each one different from the next—and IPR bears hallmarks of those other proceedings.

One of those hallmarks is a patentee's right to amend its patent claims in IPR. Under the framework that Congress created, patent owners who are concerned about the consequences that might flow from a broad reading of their patent claims may file a motion to amend to "propose a reasonable number of substitute claims" "[f]or each challenged claim." 35

U.S.C. § 316(d)(1). That ability to amend—carried over from reexamination proceedings—distinguishes IPR from proceedings in federal district courts. *See In re Yamamoto*, 740 F.2d at 1572 (recognizing the same distinction with respect to *ex parte* reexaminations).

Congress's decision to give IPR participants the right to amend creates problems for Cuozzo and its *amici* because courts have found that right sufficient to justify the broadest-reasonable-interpretation standard in other contexts. *In re Yamamoto*, 740 F.2d at 1572 (an applicant's "opportunity during reexamination to amend his claims justif[ies] using [the broadest-reasonable-interpretation standard] in reexamination proceedings"); *In re Prater*, 415 F.2d 1393, 1404–05 (C.C.P.A. 1969) (same for initial examinations). Cuozzo's response is to marginalize IPR amendments by complaining that the right to amend is more limited in IPR than it was in reexamination proceedings and by marshaling anecdotal evidence that motions to amend are sparingly granted. Pet. Br. 29–30. But no court has held that the right to amend—which has never existed in district court litigation—must be employed generously for that right to justify giving claims their broadest reasonable construction. Try as Cuozzo might to portray it otherwise, a patentee in an IPR proceeding has an absolute right to move to amend; a right that has never existed in district court proceedings. And succeeding on a motion to amend depends on a patent holder's willingness to trim the fat off overbroad claims. If the patent owner is unable to do so, then it should not prevail in IPR and its overbroad patent should not have issued in the first place.

B. Legislative history shows that Congress anticipated that the PTO might adopt the broadest-reasonable-interpretation standard for IPR.

It is not just that the PTO's policy choice to use the broadest-reasonable-interpretation standard in IPR is permissible; the AIA's legislative history suggests that Congress anticipated the PTO making that choice.

Although resort to legislative history is unnecessary to sustain the PTO's choice of the broadest-reasonable-interpretation standard (see *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 254 (1992) ("When the words of a statute are unambiguous, then, this first canon is also the last: 'judicial inquiry is complete.'")), the AIA's legislative history confirms that Congress thought that the PTO might choose that standard for IPR.

At a congressional hearing discussing amendments to the Act, Senator Jon Kyl assumed that the broadest-reasonable-interpretation standard would apply in IPR. Extolling the virtues of a provision allowing patent owners to submit written statements on the scope of their claims (35 U.S.C. § 301(a)(2)), Senator Kyl noted that the provision would root out inconsistent positions, such as "where a patent owner successfully advocated a claim scope in district court that is broader than the 'broadest reasonable construction' that he now urges in inter partes review." 157 Cong. Rec. 3428 (2011).

Cuozzo tries to minimize the import of Senator Kyl's remark by arguing that it is "a single ambiguous sentence by a single Senator." Pet. Br. 39. But when it came to the AIA, Senator Kyl was no casual observer: He was one of five or six lawmakers at the center of the

effort to improve patent law, he cosponsored an early amendment that was later folded into the AIA (157 Cong. Rec. 3421 (2011)), and was "instrumental in making improvements to the bill" that was eventually enacted into law. 157 Cong. Rec. 3433 (2011) (statement of Sen. Grassley thanking Sen. Kyl). And the statement is the opposite of "ambiguous." Senator Kyl obviously was talking about the very claim-construction standard now applied by the PTO (and challenged by Cuozzo). To Senator Kyl, it was a given that the standard would apply in IPR.

Those faint objections do not obscure that Cuozzo can point to no statement in the legislative record—by Senator Kyl or anyone else—so much as hinting that the AIA's drafters believed that any other standard would apply. Instead, Cuozzo highlights the drafters' statements that the "shift from an examinational to an adjudicative model" was expected to "expedite" the process. Pet. Br. 32; *id.* at 39 (citing Senator Kyl's statement that IPR is an "adjudicative proceeding"). Those statements, of course, say nothing about the claim-construction standard that the drafters had in mind. The only relevant legislative history supports the PTO's regulation.

C. That IPR has "adjudicatory" aspects does not mean that it must mirror district-court litigation.

With no good answer for *Chevron*, Cuozzo and its *amici* try to sidestep the deference model altogether by waving around the label "adjudicatory." They claim that because IPR serves an "adjudicatory" function, it must employ the same claim-construction standard that district courts use. Pet. Br. 26–35. That is a non-

sequitur. That IPR has some "adjudicative" aspects does not mean that it must mirror district-court litigation. The PTO has long applied the broadest-reasonable-interpretation standard in interference proceedings—which are adjudicatory in nature (*see Cuozzo*, 793 F.3d at 1278 (citing *Brand v. Miller*, 487 F.3d 862, 867–68 (Fed. Cir. 2007) and *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 500 (Fed. Cir. 1997))—so "adjudicatory" is not code for "the same as district court."

Cuozzo's efforts to remake IPR in the district court's image also cannot be squared with congressional intent. Congress enacted the AIA in part to address the inefficiencies and skyrocketing costs in patent litigation. *See* Changes to Implement Inter Partes Review Proceedings, Post-Grant Review Proceedings, and Transitional Program for Covered Business Method Patents, 77 FR 48680-01 ("The purpose of the AIA is to establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs."). Congress did not want IPR to look exactly like the system that produced those inefficiencies and costs.

That much is evident in the AIA. Instead of showing that Congress meant IPR to be district-court litigation in another skin, the statute shows that IPR differs from patent litigation in significant ways.

Perhaps most importantly, a patentee has the right to amend its claims in IPR proceedings, unlike in litigation. *See Yamamoto*, 740 F.2d at 1572 (distinguishing *ex parte* reexaminations from proceedings in federal district courts based on the same right to amend).

The standard of proof also differs in IPR: Whereas in federal court "[t]he burden is on the party asserting invalidity to prove it with facts supported by clear and convincing evidence," *Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 1365 (Fed. Cir. 1999), the challenger in IPR must prove unpatentability "by a preponderance of the evidence." 35 U.S.C. § 316(e).

Another difference: Pleading standards in district court are not as stringent as those in IPR. In federal court, a short and plain statement of the facts entitling one to relief is enough to state a claim. *See, e.g.*, *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). Not so with IPR. The threshold for getting an IPR instituted is much higher: The PTO may not institute an IPR unless "information presented in the petition" shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a).

Yet another difference: Discovery in district court is broad, and includes not only broad fact and expert discovery, but also live testimony regarding the same. *See* Fed. R. Civ. P 26(b)(1). But for IPR proceedings, Congress prescribed "that such discovery shall be limited to the deposition of witnesses submitting affidavits or declarations." 35 U.S.C. § 316(a)(5).

Still another difference: Unlike patent litigation, which averages nearly two-and-a-half years to completion (*see* PwC, 2015 Patent Litigation Study 14 (July 2014), http://www.pwc.com/us/en/forensic-services/publications/patent-litigation-study.html), IPR must be completed "not later than 1 year after" institution (absent an extension for good cause). 35 U.S.C. § 316(a)(11).

The list goes on, but it is clear that Congress did not intend IPR to be a carbon copy of patent litigation. It is a substitute for the old *inter partes* reexamination process. The legislative history makes that explicit: "The Act converts inter partes reexamination from an examinational to an adjudicative proceeding, and renames the proceeding 'inter partes review.'" H.R. REP NO. 112-98, pt. 1, at 46–47 (2011). Instead of creating a new review process from scratch, Congress took the old reexamination process (almost) down to the studs and rebuilt it into IPR. Just as a renovated house retains some features of the old, so IPR permissibly retains several features of the *inter partes* reexamination proceeding—including the broadest-reasonable-interpretation standard.

At bottom, Cuozzo's insistence on IPR's retaining "adjudicatory" aspects identical to those found in district court is a stalking horse for its efforts to convince this Court to withhold deference to the PTO's permissible choice of the broadest-reasonable-interpretation standard.

III. CUOZZO'S POLICY ARGUMENTS ARE IRRELEVANT AND OVERSTATED.

The PTO's regulation adopting the broadest-reasonable-interpretation standard for IPR was "a permissible construction" of the AIA comfortably within the agency's delegated authority. *Chevron*, 467 U.S. at 843. That is the end of the inquiry. *See Mead Corp.*, 533 U.S. at 226–27

Cuozzo knows that it loses under *Chevron*, which is why it all but ignores the doctrine and leads with a set of policy arguments about how the broadest-

reasonable-interpretation standard will turn the patent world upside down. But those policy arguments are irrelevant. "The proper *Chevron* inquiry is not whether the agency construction can give rise to undesirable results in some instances (as here *both* constructions can), but rather whether, in light of the alternatives, the agency construction is reasonable." *Barnhart v. Thomas*, 540 U.S. 20, 29 (2003). As this Court stated in *Chevron* itself—and has repeated countless times—"[w]hen a challenge to an agency construction of a statutory provision, fairly conceptualized, really centers on the wisdom of the agency's policy, rather than whether it is a reasonable choice within a gap left open by Congress, the challenge must fail." *Chevron*, 467 U.S. at 866; *see also id.* ("The responsibilities for assessing the wisdom of [an agency's] policy choices and resolving the struggle between competing views of the public interest are not judicial ones "); *Mead Corp.*, 533 U.S. at 229 ("[A] reviewing court has no business rejecting an agency's exercise of its generally conferred authority to resolve a particular statutory ambiguity simply because the agency's chosen resolution seems unwise ").

But even if the Court could consider policy arguments, they would all still fail. Cuozzo's primary complaint seems to be that the broadest-reasonable-interpretation standard is leading the PTO to invalidate more patents than ever before. Pet. Br. 34. But dealing with suspect patents is precisely what Congress intended when it passed the AIA. *In re Cuozzo Speed Techs.*, 793 F.3d at 1285 (Newman dissenting) (acknowledging that one of the AIA's goals is "facilitating the removal of patents that were improvidently granted") (citation omitted). Cuozzo

acknowledges as much in its brief. Pet. Br. 2–3 (agreeing that IPR fulfills Congress's "goal of improving the quality of patents and reducing unnecessary litigation costs."). That is reason enough to uphold the PTO's regulation.

The other policy arguments that jump back and forth between Cuozzo's and its *amici*'s briefs are more of the same and equally irrelevant. For instance, one *amici* argues that the broadest-reasonable-interpretation standard has led to the wrong result in particular cases. InterDigital Am. Br. 24–28. But the same is true for the district court standard that Cuozzo espouses.

Cuozzo argues that IPR results sometime diverge from litigation results on the same facts (Pet. Br. 34–35), but that, too, is a red herring. Potentially divergent results already exist, and have always existed, across PTO proceedings and district-court litigation. *See, e.g., Fresenius USA Inc. v. Baxter Int'l, Inc.*, 21 F.3d 1330 (Fed. Cir. 2013) (addressing claims found not invalid in district court, but later found invalid in *ex parte* reexamination). Besides, Congress recognized that potential tension and "expressly authorize[d] a stay of litigation in relation to such proceedings. It is congressional intent that a stay should only be denied in extremely rare instances." 157 Cong. Rec. 3416 (2011) (statement by Sen. Schumer).

Another *amicus* party claims that IPR is "displac[ing] district courts as a forum for adjudicating patent validity." Biotechnology Innovation Org. Am. Br. at 26–27. But that argument contradicts Congress's clear intent (which even Cuozzo recognizes) for the AIA to "limit unnecessary and counterproductive litigation

costs " 157 Cong. Rec. 3400 (2011) (statement by Sen. Leahy).

Cuozzo is correct that the PTO's decision to adopt the broadest-reasonable-interpretation standard has policy implications. But that is exactly as it should be. The PTO—"the 'agency to which Congress h[as] delegated policymaking responsibilities"—"[is] the appropriate political actor to resolve the competing interests at stake, 'within the limits of that delegation.'" *City of Arlington*, 133 S. Ct. at 1881 (quoting *Chevron*, 467 U.S. at 865).

At any rate, the patent world is not undergoing a sea change.

First, in certain instances, the broadest-reasonable-interpretation standard may very well produce the same result as the ordinary-meaning standard applied in district courts; both standards first look to claim-language's plain meaning. *See, e.g.*, *Nike, Inc. v. Adidas AG*, 812 F.3d 1326, 1346–47 (Fed. Cir. 2016) (affirming PTO's "plain meaning" conclusion that "'flat knit edge' is 'an edge of a flat knit textile element, which is itself flat knit'").

Second, the Federal Circuit serves as a backstop against unreasonable applications of the broadest-reasonable-interpretation standard. The Federal Circuit has authority to review final written decisions from IPR. 35 U.S.C. § 319. When a party takes an appeal from IPR, the Federal Circuit "conduct[s] a de novo review of the Board's determination of the broadest reasonable interpretation of the claim language." *Straight Path IP Grp., Inc. v. Sipnet EU S.R.O.*, 806 F.3d 1356, 1360 (Fed. Cir. 2015). If the

PTO misapplies the broadest-reasonable-interpretation standard—just as district courts sometimes misapply the ordinary-meaning standard—the party on the receiving end of that mistake can ask the Federal Circuit to correct it.

And the Federal Circuit is not shy about doing so. Earlier this month, the Federal Circuit considered appellate challenges by both sides after an IPR. *See Dell Inc. v. Acceleron, LLC*, ___ F.3d ___, No. 2015-1513, 2016 WL 1019075 (Fed. Cir. Mar. 15, 2016). The Federal Circuit affirmed the PTO's decisions on a number of claims but vacated the PTO's cancellation of two claims—one of which the PTO had cancelled because of purported claim-construction problems. *Id.* at *5. And in February, the Federal Circuit vacated the PTO's determination in another IPR that some claims were unpatentable, while upholding the agency's same determination about other claims. *See PPC Broadband, Inc. v. Corning Optical Commc'ns RF, LLC*, ___ F.3d ___, No. 2015-1361, 2016 WL 692368 (Fed. Cir Feb. 22, 2016). Those are just two (very recent) examples. Others abound. Appellate review of final written decisions in IPR will keep the broadest-reasonable-interpretation standard from working all the evils that Cuozzo ascribes to it.

Third, and finally. even if the sky were falling, or looked like it *might* start falling, both the PTO and Congress have the authority to change the standard in the future. Congress can always specify the claim-construction for IPR. Bills are pending that would do just that. *In re Cuozzo Speed Techs.*, 793 F.3d at 1299 (Dyk, J., concurring in denial of rehearing *en banc*) (citing, among other things, proposed legislation that

would set the claim-construction standard for IPR as something other than the broadest reasonable interpretation). Beyond that, the PTO—the agency "authorized by Congress to administer this legislation" (*Chevron*, 467 U.S. at 864)—is also free to exercise its delegated authority to select a different standard should the need arise. In fact, "the agency must consider varying interpretations and the wisdom of its policy on a continuing basis.'" *Brand X*, 545 U.S. at 981–82 (quoting *Chevron*, 467 U.S. at 863–64). The ongoing ability of Congress and the PTO to act is more than sufficient reason for the Court to stay its hand here.

* * *

"The arguments over policy that are advanced in the briefs create the impression that [Cuozzo and its *amici*] are now waging in a judicial forum a specific policy battle which they ultimately lost in the agency"—precisely what this Court warned against doing in *Chevron*. 467 U.S. at 864. It is not this Court's role to mediate that policy battle. Cuozzo should direct its policy arguments to Congress or the PTO, the political actors who actually have authority to make the judgment calls that Cuozzo desires.

IV. CONGRESS EXPRESSLY BARRED JUDICIAL REVIEW OF THE PTO'S INSTITUTION DECISIONS.

In interpreting a statute, this Court "always turn[s] first to one, cardinal canon before all others": the plain-meaning rule. *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253 (1992). The Court presumes that "Congress says in a statute what it means and means in a statute

what it says there." *Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000) (internal quotation marks omitted). "When the words of a statute are unambiguous," the "first canon is also the last: 'judicial inquiry is complete.'" *Conn. Nat'l Bank*, 503 U.S. at 254 (quoting *Rubin v. United States*, 449 U.S. 424, 430 (1981)). This Court's analysis of the appealability question should start and stop with the AIA's plain language.

In stark contrast to Congress's silence on the claim-construction standard, Congress could not have spoken more clearly in stating that the decision to institute IPR is not appealable. Section 314(d), entitled "No appeal," mandates that "[t]he determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable." 35 U.S.C. § 314(d). It is difficult to envision a clearer expression of Congressional intent. By declaring institution decisions "final and nonappealable," Congress unambiguously, and without qualification, foreclosed review of the PTO's institution decisions.

Despite that unconditional directive, Cuozzo argues that this section does not completely preclude review of institution decisions altogether but merely postpones review until the PTO issues a final written decision appealable under Section 35 U.S.C. § 319. Pet. Br 46–54. That strained interpretation cannot be squared with the plain language and purpose of the AIA. As the Federal Circuit recognized, the statute:

> provides that the decision is both "nonappealable" and "final," i.e., not subject to further review. A declaration that the decision to institute is "final" cannot reasonably be

> interpreted as postponing review until after issuance of a final decision on patentability.

In re Cuozzo Speed Techs., 793 F.3d at 1273. Without qualification, the statute forecloses judicial review of the PTO's institution decision in all instances. *See United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 242 (1989) ("The plain meaning of legislation should be conclusive ") (internal quotation marks omitted); *62 Cases, More or Less, Each Containing Six Jars of Jam v. United States*, 340 U.S. 593, 596 (1951) ("Congress expresses its purpose by words. It is for us to ascertain—neither to add nor to subtract, neither to delete nor to distort.").

Under the statutory scheme that Congress established, a patent owner dissatisfied with the PTO's final written decision is entitled to obtain review of the merits of the Board's patentability determination, but is not entitled to challenge the PTO's threshold decision to institute the proceeding. 35 U.S.C. §§ 319, 314(d). That is Congress's plain intent, not to be second-guessed or re-written by the courts.

That interpretation is not only required but is also good policy. It focuses judicial review and resources on the merits of the PTO's patentability decision while avoiding unnecessary review of threshold questions that are not relevant to the proper scope of the patent owner's exclusive rights. In other words, if the Federal Circuit ultimately affirms a meritorious patent challenge, then that patent is rightfully invalidated (and was "improvidently granted" in the first instance), regardless of any procedural issues surrounding the institution. Such a scheme supports the public's interest in efficiently eliminating invalid patents,

particularly in industries like pharmaceuticals, where invalid patents can (and do) bar market entry of competing generic products longer than Congress intended.

Essentially calling for a get-of-jail-free card, Cuozzo and its supporters seek to exploit judicial review of institution decisions in an effort to insulate invalid patents. But as the Federal Circuit recognized, a flawed decision to institute review is not a basis for setting aside a decision on the merits that a patent should not have issued in the first place. *See In re Cuozzo Speed Techs.*, 793 F.3d at 1274 ("The fact that the petition was defective is irrelevant because a proper petition could have been drafted."). Holding otherwise works a disservice not only to the consuming public, but to the integrity of the patent system as a whole.

Cuozzo and its supporters also overlook that, in many instances, an IPR petitioner could be statutorily time-barred by another AIA provision from refiling a *meritorious* petition to correct procedural issues. That separate provision forecloses a party from filing an IPR petition one year after receiving a complaint alleging infringement. 35 U.S.C. § 315(b). So under Cuozzo's rule, in many cases, a party who had successfully challenged a patent in IPR only to see that challenge undone by a post-hoc finding that the institution decision was "defective" would be foreclosed from refiling a new IPR petition. It defies logic to suggest that Congress intended that result. Yet in Cuozzo's world, despite investing substantial time and resources in a successful patent challenge, a would-be challenger would be left with no alternative but to invest even

more money and time re-challenging the patent in district-court litigation. In essence, patent owners would be able to maintain an invalid patent and escape on a technicality in the initiation of review. It is an understatement to say that this neither serves the purpose of the AIA nor the interests of the public at large, not to mention Congress's intent.

Prohibiting review of institution decisions is also consistent with the AIA's purpose. As even Cuozzo recognizes, Congress enacted the AIA to create "a more efficient and streamlined patent system [to] improve patent quality and limit unnecessary and counterproductive litigation costs " 157 Cong. Rec. 3400 (2011) (statement by Sen. Leahy); *see also* Pet. Br. 3, 16 (the "cornerstone" of the AIA was the creation of patent proceedings to "provide a reliable early decision, by technology-trained patent-savvy adjudicators, with economies of time and cost" and to "reliably resolve most issues of patent validity, without the expense and delay of district court litigation.") (quoting App. 32a–33a (Newman, J., dissenting)). Allowing patent owners to safeguard invalid patents by appealing procedural violations rather than the merits of the challenge undermines the very benefits of the efficient and cost-effective scheme that Congress sought to achieve through the AIA.

The statute's language is plain. It forecloses judicial review of the PTO's institution decisions in all instances. Simply put, there is no basis to construe "final and nonappealable" to mean conditional and appealable—the exact opposite of the clear language used in Section 314(d). *See generally In re Cuozzo Speed Techs.*, 793 F.3d at 1273. ("A declaration that the

decision to institute is 'final' cannot reasonably be interpreted as postponing review until after issuance of a final decision on patentability."). The statute's clear language alone should end the enquiry.

CONCLUSION

For all these reasons and those stated in the Respondent's separate brief, this Court should affirm the judgment below.

Respectfully submitted,

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